

REMARKS

The final Office Action mailed October 10, 2008 has been reviewed and the comments therein were carefully considered. Claims 1-11 and 27-38 have been withdrawn from consideration as being drawn to non-elected inventions. Claims 12-26 and 39-48 are currently pending.

Claim Rejections Under 35 USC §103

Claims 12-15, 17-26, 39 and 44 were rejected under 35 USC §103(a) as being unpatentable over Lebel, et al., U.S. Publication No. 2002/0016568 A1 ("Lebel"), in view of Pilarczyk U.S. Patent No. 4,766,542 ("Pilarczyk"). The Applicants respectfully disagree and traverse the rejection. Lebel is directed to an implantable medical device and an external communication device that gives an alarm to a patient when the medication remaining in the implantable medical device becomes less than a predefined low-reservoir threshold. As recognized in the Office Action, Lebel does not disclose "an appointment scheduling module automatically initiated by the drug scheduling module and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device," and does not disclose "allowing the appointment scheduling module to schedule the appointment." Further, the external communication device of Lebel is not an appointment scheduling module that is within the implantable drug delivery device as claimed in claim 12 of the present application.

It is respectfully submitted that Pilarczyk does not remedy the deficiencies of Lebel. Pilarczyk does not disclose an implantable drug delivery device. Rather, Pilarczyk is directed to "a system for contacting customers of a pharmacy automatically to remind them that their prescriptions need to be refilled...." See Abstract of Pilarczyk [emphasis added]. See also Abstract of Pilarczyk: "The voice synthesizer then reminds the customer that the prescription is due to be refilled if the medication was taken as prescribed;" Pilarczyk Col. 8, lines 11-15: "Thereafter, at block 104 the refill reminder information is obtained from the schedule file and passed to the voice synthesizer 18, and at block 106, the voice synthesizer 18 actually

communicates the refill reminder information to the party on the telephone.” Once the reminder phone call is made to a customer, the system then makes a record as to whether or not the customer acknowledges receipt of the reminder phone call – there is no automatic scheduling of an appointment taught in Pilarczyk:

Once the refill reminder message has been given, block 106, the system asks for a further response from the message receiver as shown at block 108. This response, if received, confirms that the message was delivered in full. On the other hand, if this second response from the recipient is not received, the system considers that the call was not made. In either event, as indicated at blocks 118 and 114, respectively, a record is made of the event. Thereafter, the software returns to the telephone communication block 64 which consults the schedule file, block 46, for the next scheduled call. Pilarczyk Col. 9, lines 58-68 [emphasis added].

When the full context of Pilarczyk is considered, it is clear that Pilarczyk teaches only a reminder telephone notification to a patient that their prescription needs to be refilled if the medication was taken as prescribed. Nowhere in Pilarczyk is the word “appointment” mentioned, and nowhere does Pilarczyk disclose an “appointment scheduling module to schedule the appointment” as claimed in independent claim 12. Similarly, Pilarczyk does not disclose a “scheduling module configured to activate the telemetry module to schedule an appointment” as claimed in independent claim 21. Thus, even if the proposed combination of Lebel and Pilarczyk is deemed proper, the proposed combination does not result in a scheduling module as claimed in claims 12 and 21.

There is no suggestion to combine the teachings of the cited art as advanced in the Office Action to provide the invention as claimed in pending independent claim 12, except from using the applicant’s invention as a template through a hindsight reconstruction of applicant’s claims. Even if the proposed combination is proper, it does not result in the invention of pending claim 12 because there is a conceptual link missing between the disclosures of the two cited documents: a drug device with an audible alarm (Lebel) and a reminder system that does not automatically make an appointment (Pilarczyk). Lebel discloses a goal to “enhance user interface capabilities in ambulatory medical systems and in particular for implantable infusion pump systems.” Lebel thus states a concern for greater user involvement and again it would not

have made sense to eliminate user interaction by employing automatic appointment scheduling. Consequently, without the benefit of the disclosure of the present invention, it would not have been obvious to one of ordinary skill in the art to provide an appointment scheduling module automatically initiated by a drug scheduling module, as recited in the instant claims.

Independent claim 21 recites, in part:

a scheduling module coupled to the memory and the electronics, the scheduling module configured to calculate at least one relationship among the pump scheduling criteria and monitored pump variables, the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required, and the scheduling module configured to activate the telemetry module to schedule an appointment, wherein the scheduling module is adapted to contact via the telemetry module at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient, wherein the at least one entity is selected from the group consisting of a pharmacy, a caregiver, a physician, and a hospital.

Neither Lebel nor Pilarczyk, alone or in combination, discloses the features of amended claim 21. As discussed above, Lebel teaches an external device that sounds an alarm to remind the patient to schedule an appointment, and does not disclose a scheduling module that decides automatically whether an appointment is required and initiates a telemetry module to schedule an appointment. As discussed above, at best, the system of Pilarczyk provides a pharmacy customer with a reminder phone call as to when a prescription needs to be refilled if the prescription was taken as prescribed, but does not automatically schedule an appointment. There is no teaching or suggestion by Pilarczyk that an appointment may be scheduled by a scheduling module of an implantable drug delivery device that is configured to calculate at least one relationship among the pump scheduling criteria and monitored pump variables, decide automatically whether an appointment is required, and which is configured to activate a telemetry module to schedule an appointment as claimed.

In sum, combining the features of Pilarczyk with Lebel would not result in the embodiments recited in claims 12 or 21. Neither Lebel nor Pilarczyk, alone or in combination, teach or suggest either an appointment scheduling module automatically initiated by a drug scheduling module or a scheduling module that automatically decides whether an appointment is required and initiates a telemetry module. Claims 13-15, 17-20 and 39 depend from claim 12

and claims 22-26 and 44 depend from claim 21, and are patentable over Lebel in view of Pilarczyk for at least the same reasons that claims 12 and 21 are patentable and for the additional features recited therein.

Claims 40-41 and 45-46 were rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Pilarczyk, and further in view of Mayer et al., U.S. Patent Publication No. 2002/0010567 ("Mayer"). Mayer does not remedy the deficiencies of Lebel and Pilarczyk. Mayer is directed to a set of software tools for a consumer to use for taking control of his or her own medical care. (See Abstract of Mayer). An appointment making tool is disclosed in paragraph 50 of Mayer: "This tool confirms, tracks and keeps appointments organized. For example, a patient needing an appointment for a physical." Thus, Mayer teaches appointment scheduling upon receiving a request from a *patient* for an appointment, as opposed to having a separate entity (i.e., a drug scheduling module) automatically initiating the request for an appointment. The Office Action ignores that there is no teaching in Mayer of "an appointment scheduling module automatically initiated by the drug scheduling module, and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device," as claimed in independent claim 12.

Although a pharmacist tool is disclosed in paragraph 39 of Mayer to give "an estimation of compliance and can prompt for refills to improve compliance," there is no further disclosure with respect to prompting for refills, such as how the pharmacist tool could actually provide a prompt.

There is no teaching in Mayer that the pharmacist tool (paragraph 39) communicates in any way with the appointment making tool (paragraph 50). The Office Action appears to overlook that there is not even an implicit suggestion that the ability of the pharmacist tool to prompt for refills could be adapted to initiate the appointment making tool to automatically schedule an appointment without scheduling input contemporaneously provided by the patient for an appointment to replenish a drug in a device. Indeed, paragraph 12 of Mayer states that "health care maintenance methodologies to date fail to provide individuals with the degree of control and direct involvement over one's own healthcare that can be provided from a patient-

centric resource, and paragraph 13 of Mayer states: "The present invention comprises a set of software tools that can be used by a consumer (patient or individual) to take charge of his or her own medical or health care. Systems and methods of the present invention enable a patient(s) to store, maintain and track his/her own medical data." See also the figures of Mayer, and paragraphs. 25, 30, 34, and 35 of Mayer which describe required patient input as shown in the figures of Mayer.

The visit report disclosed in paragraph 27 of Mayer requires input by a patient in order for the system to provide scheduling, prompting for and recordation of visit and follow-up visit reports. At best, automatic scheduling in Mayer is accomplished by scheduling input by the patient (paragraphs 50 and 27 of Mayer). Such scheduling is not the same as appointment scheduling automatically initiated by a drug scheduling module that has received data about the implantable drug delivery device comprising drug usage information and/or drug management data and has determined that the drug should be replenished. Accordingly, there would have been no reason for one of ordinary skill in the art to remove the patient from involvement with the appointment making tool as disclosed in paragraph 50 of Mayer and configure the pharmacist tool as disclosed in paragraph 39 of Mayer to initiate the separate appointment making tool sans patient involvement.

Claims 40-41 depend from claim 39, which in turn depends from independent claim 12. Claims 45-46 depend from claim 44, which in turn depends from independent claim 21. Claims 40-41 and 45-46 are patentable over Lebel in view of Pilarczyk, and further in view of Mayer for at least the same reasons as amended claims 12 and 21 are patentable and for the additional features recited therein.

Claim 16 was rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Pilarczyk, and further in view of Akers, et al., U.S. Patent No. 6,112,182 ("Akers"). Claim 16 depends from claim 12. Akers is directed to a data processing system for use in managing healthcare and does not remedy the deficiencies of Lebel and Pilarczyk with respect to claim 12. Therefore claim 16 is patentable over Lebel in view of Pilarczyk and further in view of Akers for at least the same reasons as amended claim 12, and for the additional features recited therein.

Claims 42-43 and 47-48 were rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Pilarczyk, and further in view of Cummings, Jr., et al., U.S. Patent No. 6,345,260 ("Cummings, Jr."). Claims 42-43 depend from claim 12 and claims 47-48 depend from claim 21. Cummings, Jr. is directed to an appointment scheduling interface for booking appointments with professionals. (See Col. 1, lines 13-16 of Cummings, Jr.) Cummings, Jr. does not remedy the deficiencies of Lebel and Pilarczyk with respect to either claim 12 or claim 21. Cummings, Jr. does not teach or suggest at least an appointment scheduling module automatically initiated by a drug scheduling module or a scheduling module that initiates a telemetry module to schedule an appointment. Rather, Cummings, Jr., discloses a

"[C]all center, to which clients can call through conventional telephone lines. (Col. 6, lines 46-47) "While client 10b is on the line, call center 11 can log onto the Web from any Web browser. With proper security clearance and verification, server 15 permits access to online master schedule database 16, which contains and displays the appointment times and dates for all physicians on the system, i.e., showing those times when these physicians are willing to accept tentative appointment bookings." (Col. 8, lines 1-7)

Appointment scheduling is therefore disclosed by Cummings, Jr. to be initiated by a *client call* to a call center.

Accordingly, none of Lebel, Pilarczyk, or Cummings, Jr., either alone or in combination, teaches or suggests the inventions of independent claims 12 or 21. Claims 42-43 depend from claim 12 and claims 47-48 depend from claim 21, and are patentable over Lebel in view of Pilarczyk and Cummings, Jr. for at least the same reasons as amended claims 12 and 21 and for the additional features recited therein. Reconsideration and withdrawal of the 35 USC §103(a) rejections are respectfully requested.

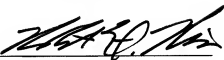
CONCLUSION

Applicants therefore respectfully request reconsideration of the pending claims and a finding of their allowability. A notice to this effect is respectfully requested. The Examiner is welcome to contact via telephone the undersigned should it be helpful to facilitate prosecution of the application.

Respectfully submitted,

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